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David Rice, Acting Director
Division of Outpatient Care
Centers for Medicare & Medicaid Services
Mailstop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

VIA ELECTRONIC DELIVERY

Dear Mr. Rice,

The American Academy of Ophthalmology (Academy), American Society of Cataract and Refractive Surgery (ASCRS), and the Outpatient Ophthalmic Surgery Society (OOSS) are reaching out regarding the bundling of ophthalmic drugs or devices once pass-through status has expired. At this time CMS has not developed a policy that provides separate Medicare Part B coverage and payment for drugs that are administered at the time of ophthalmic surgery and have FDA-approved indications for the treatment/prevention of postoperative issues. We are concerned about adequate patient access to care. Without an updated packaging policy, CMS is missing the opportunity to reduce patient eye drop burden and increase positive patient outcomes. Many ophthalmic surgery patients are aged, have memory limitations, significant physical conditions, and comorbidities. Medications, administered by the surgeon at the time of surgery, are a valuable treatment alternative to post-operative drops and have the potential to reduce or eliminate the need for patient-administered post-operative medication. **We believe it is inappropriate to package these treatments in with the surgical procedure facility fee and urge CMS reconsider this policy decision and unpackage drugs with postoperative (not surgical) indications. These drugs are unique and have benefits well beyond traditional surgical supplies.**

The goal for pass-through payments is to facilitate patient access to new devices and drugs. After a drug or device's pass-through status expires, it may be packaged and reimbursed as part of the facility fee for which the hospital or ASC would otherwise receive payment. However, there are major issues with this process which could reduce patients access to care. The facility fee rarely covers the cost of the drug or device. ASCs operating on tight margins may be unable to provide patients with access to all FDA-approved medications with postoperative indications because they are too costly to include in the bundled facility fee. As you may be aware, when a drug's pass-through status expires, its use often declines once its cost is packaged into the ambulatory payment classification (APC) payment because of the ASC's inability to afford the drug.

We believe there is precedent for separate payment for drugs when they have certain indications. CMS does have a policy that allows separate payment for nonopioid pain management drugs, such as Omidria, that function as surgical supplies when furnished in the ASC setting. This policy excludes drugs meeting this definition from packaging under the ASC payment system. Because this policy avenue exists, we encourage CMS to revisit the issue of packaging drugs used in ophthalmic surgery where there is a postoperative (not surgical) application aside from nonopioid pain management which will provide fair reimbursement and preserve patient access.

For example, the primary utility of *(Dexamethasone, lacrimal ophthalmic insert, 0.4 mg (Dextenza®)*, is reduction of postoperative inflammation and associated complications following ophthalmic surgery. *(Dexamethasone, lacrimal ophthalmic insert, 0.4 mg (Dextenza®)* is approved for the treatment of both ocular inflammation and pain following ophthalmic surgery. Additionally, *DEXYCU® (dexamethasone intraocular suspension) 9%* is a corticosteroid also indicated for the treatment of postoperative inflammation. These extended-release medications for post-operative indications like inflammation and/or pain are neither a supply nor integral to the ophthalmic surgical procedure and thereby do not meet the criteria for packaging. The Academy believes extended-release medications intended for post-surgical care should be granted separate payment.

We are concerned that the packaging of drugs like *(Dexamethasone, lacrimal ophthalmic insert, 0.4 mg (Dextenza)* and *DEXYCU® (dexamethasone intraocular suspension) 9%* when there is a clear post-surgical benefit will reduce access to clinically appropriate and innovative therapies for Medicare beneficiaries. Limiting access these drugs miss the opportunity to reduce the postoperative drop burden for many patients who would otherwise have to take drops four times a day for several weeks. This has the potential to reduce the risk of irritation and poor outcomes related to inadequate adherence to the eyedrop regimen. **We urge CMS to revisit the important issue of packaging drugs used in ophthalmic surgery where there is a post-operative approved indication in the upcoming *CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System* proposed rule.**

We look forward to working with CMS to develop policy that provides separate payment for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat/prevent post- operative issues. We appreciate this opportunity to express our concerns if you have additional questions, please reach out to Kayla L. Amodeo, PhD, Health Policy Director, at kamodeo@aao.org.

Sincerely,

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Medical Director, Governmental Affairs
American Academy of Ophthalmology

Parag Parekh, MD, MPA
Chairman, Government Relations Committee
American Society of Cataract and Refractive Surgery

Cathleen McCabe, MD
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